SEP 1 3 2007

510(k) SUMMARY

Date of Summary September 4, 2007

Product Name Bio-Rad MRSA*Select*
A selective medium for the detection and direct identification of methicillin-resistant *Staphylococcus aureus*.

Sponsor
Bio-Rad
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92430 Marnes-la-Coquette
France

Correspondent
MDC Associates, LLC
Fran White, Regulatory Consultant
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Device

MRSA*Select* is substantially equivalent to BBL CHROMagar MRSA (510(k) number: K042812)

Manufacturer: Becton Dickinson & Company
Product: BBL CHROMagar MRSA

Product Attribute	Bio-Rad MRSA*Select*™	BBL CHROMagar MRSA	Substantially Equivalent?
Intended use	MRSA*Select* is a selective and differential chromogenic medium for the qualitative detection of nasal colonization of methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings.	CHROMagar is a selective and differential chromogenic medium for the qualitative detection of nasal or colonization of methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings.	√
Sample	Nasal swabs	Nasal swabs	√
Test methodology	Selective Media	Selective Media	√

PRODUCT DESCRIPTION:
Methicillin-resistant *Staphylococcus aureus* is a major cause of nosocomial and life threatening infections which have been associated with significantly higher rates of mortality and morbidity. The Bio-Rad MRSA*Select* is a selective and differential chromogenic culture medium for the qualitative detection of MRSA from anterior nares specimens.

INTENDED USE:
MRSA*Select* is a selective and differential chromogenic medium for the qualitative detection of nasal colonization of methicillin resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test can be performed on anterior nares specimens from patients and healthcare workers to screen for MRSA colonization. MRSA*Select* is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection.

SUMMARY OF TECHNOLOGY:
MRSA*Select* is a selective medium for the detection and direct identification of MRSA. The selectivity of this medium is based on the presence of an antibiotic/antifungal mixture and an optimized salt concentration and that inhibits the growth of yeast and the majority of Gram negative and Gram positive bacteria with the exception of methicillin-resistant staphylococci. Identification is based on the cleavage of a chromogenic substrate by a specific enzymatic activity of *Staphylococcus aureus* leading to a strong pink coloration of the *Staphylococcus aureus* colonies.

At 24 hours incubation time methicillin-resistant *Staphylococcus aureus* produce small pink colonies on MRSA*Select*. Coagulase negative methicillin-resistant staphylococci that do not metabolize the chromogenic substrate appear as colorless or white colonies (possibly light pink). Methicillin sensitive staphylococci (MSS) are inhibited.

PERFORMANCE DATA:
Performance of MRSA*Select* was evaluated at three geographically diverse hospitals with fresh surveillance specimens of the anterior nares samples. A total of 3013 nares samples were evaluated. MRSA*Select was compared* to routine culture which was defined as isolation on Staphylococci on Trypticase Soy Agar with 5% blood, with identification confirmed by Coagulase and Oxacillin susceptibility and BD BBL™ CHROMagar™ MRSA. Culture results and MRSA*Select* results were reported at 24 hours, BD ChromAgar was read at 48 hours in accordance with manufacturers instructions. Product performance is summarized below:

Comparison with Routine Culture

		Routine Culture pos	neg	total		
					sen	96%
	pos	227	33	260	spec	98%
MRSA Select						
24 hours	neg	10	1502	1512	ppv	87%
					npv	99%
		237	1535	1772		

Comparison with CHROMagar

		CHROMagar pos	neg	total		
					sen	94%
	pos	297	24	321	spec	99%
MRSA Select						
24 hours	neg	18	2674	2692	ppv	92%
					npv	99%
		315	2698	3013		

Interference Study

Commonly used medicinal substances and commonly used transport devices were evaluated for potential interference of the chromogenic reaction of the MRSA*Select* medium. No interference was noted. Commonly used nasal sprays at concentrations may inhibit growth that is unrelated to medium performance.

STATEMENT OF SAFETY AND EFFICACY:

MRSA*Select* was tested and compared to routine culture, identification and susceptibility methods, and BD CHROMagar. MRSA*Select,* when testing 3013 surveillance samples, demonstrated, at 24 incubation, 98% agreement to routine culture, identification and susceptibility and 99% as compared to CHROMagar.

Bio-Rad confirms that any/all data provided in this submission may be released upon request.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 3 2007

Bio-Rad
c/o Ms. Fran White
Regulatory Consultant
MDC Associates, LLC
163 Cabot Street
Beverly, MA 01915

Re: k070361
Trade/Device Name: MRSA*Select*
Regulation Number: 21 CFR 866.1700
Regulation Name: Culture Medium for Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Code: JSO
Dated: September 5, 2007
Received: September 6, 2007

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070361

Device Name: MRSA*Select*

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K070361